

66. An isolated nucleic acid probe or primer that comprises at least 100 nucleotide residues, has a nucleotide sequence identical to at least 100 consecutive nucleotide residues of SEQ ID NO: 45 or 46, or a complement thereof, and hybridizes in 6× sodium chloride/sodium citrate (SSC) at about 45°C, followed by one or more washes in 0.2× SSC, 0.1% SDS at 50°C with a nucleic acid molecule consisting of the nucleotide sequence of SEQ ID NO: 45 or 46 or a complement thereof. --

### **REMARKS**

Claims 1-7, 12, and 24-66 are pending following entry of this Amendment. Claims 1, 2, 12, 29-33, 35-38, and 40 have been amended. Claims 41-66 have been added. Claims 1, 43, and 66 are the only independent claims. The amendments and additions made herein do not include new matter, as indicated in the following section.

#### **Support in the Specification**

The title of the invention has been deleted and replaced with a more descriptive one, per the Examiner's suggestion.

Claim 1 has been amended to include the functional recitation that the recited nucleic acid molecule encodes a polypeptide that exhibits lipase activity. This recitation is disclosed in the specification, for example at page 76, lines 17-30.

In claims 1, 2, 29-32, and 35-37, the phrase "amino acid sequence encoded by SEQ ID NO: 45 or 46" has been modified in each instance by deleting "45 or". Each of SEQ ID NOs: 45 and 46 encode the same amino acid sequence, so this amendment merely removes redundancy.

Claims 30 and 31 were amended to recite what was already inherently recited therein (i.e., that the recited nucleic acid encodes a polypeptide comprising the recited amino acid residues).

Claim 33 was amended to recite that the encoded amino acid residues comprise an immunogenic portion of the protein encoded by SEQ ID NO: 46. This claim is supported in

the specification, for example at the paragraph bridging pages 82 and 83 of the specification. New claims 41 and 42 are similarly supported.

Claims 38 and 40 (which recite that the encoded polypeptide exhibits lipase activity) were redundant in view of the amendment of claim 1, and have been amended to depend indirectly from new independent claim 43 (which recites that the encoded polypeptide comprises an immunogenic portion of the protein encoded by SEQ ID NO: 46).

New independent claim 43 is identical to claim 1, except that it recites that the nucleic acid molecule encodes an immunogenic portion of the protein having the amino acid sequence encoded by SEQ ID NO: 46 (i.e., rather than that it encodes a polypeptide that exhibits lipase activity, as in claim 1). This recitation is supported in the specification, for example at the paragraph bridging pages 82 and 83 of the specification.

New dependent claims 44-65 substantially mirror the recitations of dependent claims 39, 24-31, 33, 32, 2-6, 34, 7, 12, and 35-37, respectively, with the following exceptions. New claim 53 recites that the encoded polypeptide exhibits lipase activity (whereas mirrored claim 33 recites that it includes an immunogenic portion). New claim 62 is a method of producing an immunogenic portion (whereas mirrored claim 12 is a method of producing a polypeptide that exhibits lipase activity). The recitations of claims 53 and 62 are also supported in the specification at the paragraph bridging pages 82 and 83 of the specification.

New independent claim 66 is supported in the specification, for example at the paragraph bridging pages 73 and 74.

For the foregoing reasons, the Applicants respectfully contend that the amendments and additions made herein do not include new matter.

### **Overview of this Amendment**

The Applicants believe that agreement was reached during the October 15, 2002 interview that the application includes allowable subject matter, relating to three areas. These areas are:

I) Nucleic acid molecules that encode a polypeptide which exhibits lipase activity. Claims 1-7, 12, 24-37, 39, 41, and 42 relate to this subject matter. Claim 1 is the only independent claim in this group.

II) Nucleic acid molecules that encode an immunogenic portion of the protein encoded by SEQ ID NO: 46. Claims 38, 40, and 43-65 relate to this subject matter. Claim 43 is the only independent claim in this group.

III) Nucleic acid molecules that include a significant region of sequence identity with SEQ ID NO: 45 or 46 and are useful as probes or primers. Independent claim 66 relates to this subject matter.

Although the Applicants believe that additional subject matter is allowable (e.g., relating to a broader range of probe, primer, and antisense polynucleotides), the Examiners indicated that they were not inclined to allow claims directed to that subject matter at this time. Accordingly, the Applicants have canceled claims directed to this subject matter without prejudice, in order to advance prosecution of this application to allowance as expeditiously as possible.

The Applicants have the following responses to the issues raised by the Examiner in the Final Office Action dated May 20, 2002.

#### **References Cited on Form PTO-1449**

The Examiner has not returned initialed copies of the two PTO-1449 forms to indicate that the references cited on those forms have been considered. The Applicants provided a copy of each Form PTO-1449 that has been filed during the prosecution of this application, as well as copies of the references cited on those forms with the response to the previous Office Action which was mailed on January 14, 2002 (Paper No. 8). During the October 15, 2002 interview, the Examiner suggested that another copy of the cited references should be forwarded **by hand delivery** to her for consideration. Under separate cover, the Applicants are forwarding a copy of each of these references to the Examiner for her consideration. Consideration of the references and return of initialed forms PTO-1449 are requested.

**Claims 38 and 40**

The Examiner previously objected that claims 38 and 40 were substantially identical. Claims 38 and 40 have been amended to depend from separate claims, and the Examiner's objection is believed to be moot.

**Rejections Pursuant to 35 U.S.C. § 112, First Paragraph**

The Examiner rejected claims 1, 3-7, 12, 24-28, 30-34, and 36-40 pursuant to the first paragraph of 35 U.S.C. § 112. In the Examiner's view, the claims are not enabled because the claims include within their scope molecules that do not exhibit lipase activity or some other appropriate functionality.

Each of the rejected claims presently recites (or depends from a claim that recites) that the encoded polypeptide exhibits lipase activity. The Examiner's rejection is believed to be moot for this reason.

The Examiner's rejection is also believed to be inapplicable to the other pending claims. Each pending claim recites that the nucleic acid molecule i) encodes a polypeptide that exhibits lipase activity, ii) encodes an immunogenic portion of the protein encoded by SEQ ID NO: 46, or iii) is a probe or primer that has a nucleotide sequence identical to at least 100 consecutive residues of SEQ ID NO: 45 or 46 or its complement. Because the Examiners indicated that all three of these recitations limited the claimed subject matter to that which the Examiners consider allowable, all of the pending claims are believed to be sufficiently enabled and in condition for allowance.

**Summary**

The Applicants respectfully contend that each of claims 1-7, 12, and 24-66 is in condition for allowance. Reconsideration and allowance of all of these claims are respectfully requested at the earliest possible time.

Respectfully submitted,

SEAN A. MCCARTHY ET AL.

21 October 2002

(Date)

By: 

GARY D. COLBY, Ph.D., J.D.

Registration No. 40,961

AKIN, GUMP, STRAUSS, HAUER & FELD, L.L.P.

One Commerce Square

2005 Market Street - 22nd Floor

Philadelphia, PA 19103-7086

Telephone: 215-965-1200

**Direct Dial: 215-965-1285**

Facsimile: 215-965-1210

E-Mail: gcolby@akingump.com

Enclosures: Petition for Extension of Time  
Marked-Up Copy of Claims Amended  
Clean Copy of Claims, as Amended

U.S. Application Serial  
No. 09/333,159

Attorney Docket No. 10147-6  
(MBI099-030)

**Marked-Up Copy of Claims Amended  
in the Amendment Filed in Response to the  
Office Action Dated 20 May 2002**

1. (Thrice Amended) An isolated nucleic acid molecule that encodes a polypeptide which exhibits lipase activity, wherein the isolated nucleic acid molecule is selected from the group consisting of:

a) a nucleic acid molecule having a nucleotide sequence which is at least 90% identical to the nucleotide sequence of SEQ ID NO: 45 or 46, or a complement thereof;

b) a nucleic acid molecule comprising at least 100 nucleotide residues and having a nucleotide sequence identical to at least 100 consecutive nucleotide residues of SEQ ID NO: 45 or 46, or a complement thereof;

c) a nucleic acid molecule which encodes a polypeptide comprising the amino acid sequence encoded by SEQ ID NO: ~~45 or~~ 46;

d) a nucleic acid molecule which encodes at least 20 consecutive amino acid residues of the amino acid sequence encoded by SEQ ID NO: ~~45 or~~ 46; and

e) a nucleic acid molecule which encodes a variant of the amino acid sequence encoded by SEQ ID NO: ~~45 or~~ 46, wherein the nucleic acid molecule hybridizes in 6× sodium chloride/sodium citrate (SSC) at about 45°C, followed by one or more washes in 0.2× SSC, 0.1% SDS at 50°C with a nucleic acid molecule consisting of the nucleotide sequence of SEQ ID NO: 45 or 46 or a complement thereof.

2. (Twice Amended) The isolated nucleic acid molecule of claim 1, which is selected from the group consisting of:

U.S. Application Serial  
No. 09/333,159

Attorney Docket No. 10147-6  
(MBI099-030)

a) a nucleic acid having the nucleotide sequence of SEQ ID NO: 45 or 46, or a complement thereof; and

b) a nucleic acid molecule which encodes the amino acid sequence encoded by SEQ ID NO: 45 or 46.

12. (Thrice Amended) A method for producing a polypeptide ~~selected from the group consisting of:~~

~~a) a polypeptide comprising the amino acid sequence encoded by SEQ ID NO: 45 or 46;~~

~~b) a polypeptide comprising at least 20 contiguous amino acids of the amino acid sequence encoded by SEQ ID NO: 45 or 46; and~~

~~c) a variant of a polypeptide comprising the amino acid sequence encoded by SEQ ID NO: 45 or 46, wherein the polypeptide is encoded by a nucleic acid molecule which hybridizes in 6× SSC at about 45°C, followed by one or more washes in 0.2× SSC, 0.1% SDS at 50°C with a nucleic acid molecule consisting of the nucleotide sequence of SEQ ID NO: 45 or 46, or a complement thereof;~~

that exhibits lipase activity, the method comprising culturing the host cell of claim 5 under conditions in which the nucleic acid molecule is expressed.

29. (Amended) The isolated nucleic acid molecule of claim 1, wherein the nucleic acid molecule encodes a polypeptide comprising the amino acid sequence encoded by SEQ ID NO: 45 or 46.

U.S. Application Serial  
No. 09/333,159

Attorney Docket No. 10147-6  
(MBI099-030)

30. (Twice Amended) The isolated nucleic acid molecule of claim 1, wherein the nucleic acid molecule encodes a polypeptide comprising at least 20 consecutive amino acid residues of the amino acid sequence encoded by SEQ ID NO: ~~45 or~~ 46.

31. (Amended) The isolated nucleic acid molecule of claim 30, wherein the nucleic acid molecule encodes a polypeptide comprising at least 25 consecutive amino acid residues of the amino acid sequence encoded by SEQ ID NO: ~~45 or~~ 46.

32. (Twice Amended) The isolated nucleic acid molecule of claim 1, wherein the nucleic acid molecule encodes a variant of the amino acid sequence encoded by SEQ ID NO: ~~45 or~~ 46, wherein the nucleic acid molecule hybridizes in 6× SSC at about 45°C, followed by one or more washes in 0.2× SSC, 0.1% SDS at 50°C with a nucleic acid molecule consisting of the nucleotide sequence of SEQ ID NO: 45 or 46 or a complement thereof.

33. (Amended) The isolated nucleic acid molecule of claim 30, wherein the ~~polypeptide exhibits lipase activity~~ consecutive amino acid residues comprise an immunogenic portion of the protein having the amino acid sequence encoded by SEQ ID NO: 46.

35. (Amended) The method of claim 12, wherein the polypeptide comprises the amino acid sequence encoded by SEQ ID NO: ~~45 or~~ 46.

36. (Amended) The method of claim 12, wherein the polypeptide comprises at least ~~18~~ 20 contiguous amino acids of the amino acid sequence encoded by SEQ ID NO: ~~45 or~~ 46.

37. (Twice Amended) The method of claim 12, wherein the polypeptide is a variant of the polypeptide encoded by SEQ ID NO: ~~45 or~~ 46, wherein the polypeptide is encoded by a nucleic acid molecule which hybridizes in 6× SSC at about 45°C, followed by one



U.S. Application Serial  
No. 09/333,159

Attorney Docket No. 10147-6  
(MBI099-030)

or more washes in 0.2× SSC, 0.1% SDS at 50°C with a nucleic acid molecule consisting of the nucleotide sequence of SEQ ID NO: 45 or 46, or a complement thereof.

38. (Amended) The method of claim-~~12~~ 64, wherein the polypeptide exhibits lipase activity.

40. (Amended) The method of claim-~~12~~ 65, wherein the polypeptide exhibits lipase activity.